

Evaluation Report for Category B, Subcategory 2.1, 2.3 and 2.4 Application

Application Number: 2015-1969
Application: B.2.1 - Change Guarantee
B.2.3 - Change Identity of Formulants
B.2.4 - Change Proportion of Formulants
Product: Bumper 432 EC
Registration Number: 28017
Active ingredients (a.i.): Propiconazole
PMRA Document Number : 2648486

Purpose of Application

The purpose of this application was to amend the guarantee and chemical specifications of Bumper 418, and as a result renaming the product Bumper 432 to be in line with the new guarantee.

Chemistry Assessment

Bumper 432 EC is formulated as an emulsifiable concentrate containing propiconazole at a nominal concentration of 432 g/L. This end-use product has a density of 1.062 g/mL (at 26°C) and pH of 4-5. The required chemistry data for Bumper 432 EC have been provided, reviewed and found to be acceptable.

Health Assessments

The acute toxicity of Bumper 432 EC is slight via the oral route and low via the dermal and inhalation routes of exposure in rats. It is mildly irritating to the eyes and slightly irritating to the skin of rabbits. It is not a skin sensitizer in guinea pigs.

The occupational exposure from the use of Bumper 432 EC on wheat, barley, oats, canola, corn, soybeans (grown for seed), dry edible beans, canary seed, peaches, nectarines, plums, apricots, sweet and sour cherries, highbush and lowbush blueberries, Saskatoon berries, cranberries, caneberries, strawberries, rutabagas, asparagus, western red cedar and Kentucky bluegrass grown for seed was assessed. No health risks of concern were identified or are expected when workers follow the label directions and wear the personal protective equipment stated on the label.

Environmental Assessment

A new environmental assessment was not required for this application as the change in formulation is acceptable from an environmental perspective.

Value Assessment

Based on the similarity of the proposed formulation to that of the precedent product formulation, and use history information provided, the performance of Bumper 432 EC Fungicide is expected to be acceptable. The registration of Bumper 432 EC Fungicide is therefore supported from a value perspective.

Conclusion

The PMRA has reviewed information provided in support of the application to amend the guarantee and chemical specifications of Bumper 418, and as a result renaming the product Bumper 432 to be in line with the new guarantee. Based on this review, the amendment to the guarantee is acceptable.

References

2534098	2015, U.S. Use History Bumper 432-19may2015, DACO: 10.2.4
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2534105	2011, Bumper 40.8 VC Acute Oral Toxicity Study (UDP) In Rats, DACO: 4.6.1
2534106	2011, Bumper 40.8 VC Acute Dermal Toxicity Study In Rats, DACO: 4.6.2
2534107	2011, Bumper 40.8 VC Acute Inhalation Toxicity Study In Rats, DACO: 4.6.3
2534108	2011, Bumper 40.8 VC Acute Eye Irritation Study In Rabbits, DACO: 4.6.4
2534109	2011, Bumper 40.8 VC Acute Dermal Irritation Study In Rabbits, DACO: 4.6.5
2534110	2011, Bumper 40.8 VC Skin Sensitization Study In Guinea Pigs, DACO: 4.6.6

2534099	2015, Chemistry-3.1.1-4,,3.5.4-5-Bumper VOC, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.4,3.5.5
2534101	2011, Bumper 41VC (Propiconazole) Fungicide: Product Properties, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
2534102	2011, Final Report for " Physical and Chemical Characteristics of Bumper 40.8 VC", DACO: 3.5.1,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI
2534103	2012, Storage Stability and Corrosion characteristics pf Bu,per 40.8 VC, DACO: 3.5.10,3.5.14
2534104	2011, Bumper 41VC (Propiconazole) Fungicide: Product Properties, DACO: 3.5.12,3.5.13,3.5.15
2564044	2015, Chemistry-3.1.1-4,,3.5.4-5-Bumper VOC-11sept2015, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.4,3.5.5

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